HFI-35 4/25/97

DEPARTMENT OF HEALTH & HUMAN SERVICES M340N Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

April 21, 1997

**WARNING LETTER**
**CIN-WL-97-325**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Jennifer L. Helligrath, Owner
B-Zhars Salon
229 W. McMillan
Cincinnati, OH 45219

Dear Ms. Helligrath:

The Food and Drug Administration (FDA) conducted an inspection of your tanning center at 229 W. McMillan, Cincinnati, Ohio, on 4/1/97 and 4/2/97. The investigator documented that the tanning beds do not comply with the Federal Standard for Sunlamp Products, Title 21, **Code of Federal Regulations** Part 1040.20. This causes the tanning beds to be adulterated within the meaning of Section 501(e) of the Federal Food, Drug and Cosmetic Act (the Act) as the tanning beds fall below the quality that they are represented to possess.

The following items of non-compliance with the standards were found:

- The tanning beds in Room 4 and 6 had defective non-working timers. The beds operated by an on/off switch only.
- The tanning beds are missing required labeling such as a warning statement with "DANGER-Ultraviolet radiation xxx;" recommended exposure positions and schedules; and designation of the ultraviolet lamp type to be used in the product.
- Bulb compatibility could not be shown for the mix of sun lamp bulbs found in the beds.
- No User Instruction-Operator's Manuals are available for each tanning bed model to aid in the beds' safe operations.

This letter is not intended to be an all-inclusive list of deficiencies at your tanning center. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 1141 Central Parkway, Cincinnati, Ohio, 45202, to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

LEB/pjk